

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CAMDEN VICINAGE**

JOSEPH BARRETT,

Plaintiff,

v.

TRI-COAST PHARMACY, INC., et al.

Defendants.

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Civil No. 18-14872 (RBK/AMD)

OPINION

KUGLER, United States District Judge:

This matter comes before the Court on Plaintiff’s second motion for Default Judgment (Doc. No. 21). The motion is unopposed. For the reasons set forth below, Plaintiff’s motion is **DENIED** without prejudice.

I. BACKGROUND

A. Factual Background

Joseph Barrett (“Plaintiff”) is an otherwise healthy 57-year-old adult residing in New Jersey. (Doc. No. 14, Am. Compl. at ¶ 1). In December of 2016, he was prescribed injectable human chorionic gonadotropin (“hCG”), which was purportedly developed, manufactured, and sold by Defendant Tri-Coast Pharmacy, Inc.—a Florida corporation that manufacturers,

distributes, and sells pharmaceutical products to medical facilities and pharmacies throughout the United States, including New Jersey, for use on patients as injections. (*Id.* at ¶¶ 2,9). At the time Plaintiff was prescribed the pharmaceutical, Defendant Kevin O’Connell, a citizen of South Carolina, was a pharmacist for and principal and/or officer of Tri-Coast Pharmacy. (*Id.* at ¶¶ 5, 21). Shortly after administering the hCG, Plaintiff developed symptoms including diarrhea, gas, bloating, pain, joint pain, and pain in various parts of his body. (*Id.* at ¶ 11). He received treatment by his physician to alleviate these symptoms in December of 2016 and the years following. (*Id.*). However, subsequent testing revealed a bacterial infection and in January of 2017, Plaintiff underwent surgery for infective synovitis of the wrist. (*Id.* at ¶¶ 12, 13).

In May of 2017, Tri-Coast Pharmacy recalled products due to bacterial contamination. (*Id.* at ¶ 14). That same month, Plaintiff received a recall notice from Tri-Coast Pharmacy which indicated that the injectable hCG he had been prescribed was subject to the recall. (*Id.* at ¶ 15). It is believed the contamination stemmed from the unsanitary environment in which Defendant Tri-Coast Pharmacy manufactured its pharmaceuticals. (*Id.* at ¶¶ 24–25). Defendants allegedly did not disclose the unsanitary nature of their facilities to the hospitals, physicians, and consumers to which that their products were distributed to. (*Id.* at ¶ 26). As a result, Plaintiff could not discover the cause of his bacterial infection and infective synovitis until after he received the recall notice in May of 2017. (*Id.* at ¶ 27).

B. Procedural Posture

October 11, 2018, Plaintiff filed his complaint against Defendant Tri-Coast Pharmacy and Defendant Kevin O’Connell alleging (1) violations of the New Jersey Products Liability Act; (2) breach of implied warranties; (3) breach of express warranties; (4) negligence; (5) negligence per se; (6) fraud under the New Jersey Consumer Fraud Act and NJSA 56:8-1; (7) intentional

infliction of emotional distress; and (8) negligent infliction of emotional distress. (Doc. No. 1). Plaintiff sought damages for past and future medical expenses, loss of earnings, and pain and suffering. (*Id.* at ¶¶ 29–33). Subsequently, on December 6, 2018, Defendant Tri-Coast Pharmacy and Defendant Kevin O’Connell were served with a copy of the summon and complaint. (Doc. No. 4). Defendants were required to answer, move, or otherwise respond to Plaintiff’s complaint by December 27, 2018. Defendants’ did not do so and consequently, Plaintiff requested an entry of default from the Clerk of the Court on March 14, 2019. (Doc. No. 6). The Clerk granted Plaintiff’s request for entry of default that same day. Plaintiff then moved for an entry of default judgment on March 28, 2019. (Doc. No. 8). This Court denied Plaintiff’s motion as moot because he failed to properly allege diversity jurisdiction. (Doc. No. 9). Plaintiff amended the complaint but still failed to properly allege diversity jurisdiction causing this Court to dismiss the case without prejudice. (Doc. No. 11). Plaintiff moved for reconsideration, which this Court granted on October 4, 2019. (Doc. No. 13). The complaint was then amended to properly plead diversity jurisdiction. (Doc. No. 14). On March 2, 2020, Plaintiff made his second request for entry of default by the Clerk of the Court. (Doc. No. 17). It was granted on March 9th. Plaintiff now moves for an entry of default judgment against Defendants Tri-Coast Pharmacy and Kevin O’Connell. (Doc. No. 21).

II. Legal Standard

Federal Rule of Civil Procedure 55(b)(2) allows the Court, upon a plaintiff’s motion, to enter default judgment against a defendant that has failed to plead or otherwise defend a claim for affirmative relief. The Court should accept as true all well-pleaded factual allegations in the complaint by virtue of the defendant’s default except for those allegations pertaining to damages. *Chanel, Inc. v. Gordashevsky*, 558 F. Supp. 2d 532, 535–36 (D.N.J. 2008) (citing *Comdyne I*,

Inc. v. Corbin, 908 F.2d 1142, 1146 (3d Cir. 1990)). The Court also does not adopt a plaintiff's legal conclusions because whether the facts set forth an actionable claim is for the Court to decide. *Doe v. Simone*, No. 12-5825, 2013 WL 3772532, at *2 (D.N.J. July 17, 2013).

While the decision to enter default judgment is left principally to the discretion of the district court, there is a well-established preference in the Third Circuit for cases to be decided on the merits rather than by default judgment whenever practicable. *Hritz v. Woma Corp.*, 732 F.2d 1178, 1180–81 (3d Cir. 1984). Consequently, the Court must address a number of issues before deciding whether a default judgment is warranted in the instant case. If the Court finds default judgment to be appropriate, the next step is for the Court to determine a proper award of damages. *Slaughter v. Moya*, No. 17-6767, 2018 WL 3742622, at *1 (D.N.J. Aug. 7, 2018).

III. Discussion

A. Court's Jurisdiction

First, the Court must determine whether it has both subject-matter jurisdiction over Plaintiff's cause of action and whether it may exercise personal jurisdiction over Defendants. *U.S. Life Ins. Co. in N.Y.C. v. Romash*, No. 09-3510, 2010 WL 2400163, at *1 (D.N.J. June 9, 2010). This is to prevent issuance of a void judgment and a collateral attack. *See id. citing Williams v. Life Sav. & Loan*, 802 F.2d 1200, 1202–03 (10th Cir. 1986).

This Court has subject-matter jurisdiction over the case pursuant to 28 U.S.C. § 1332. To establish diversity jurisdiction under 28 U.S.C. § 1332, “the party asserting jurisdiction must show that there is complete diversity of citizenship among the parties” as well as an amount in controversy that exceeds the statutory threshold. *Schneller v. Crozer Chester Med. Ctr.*, 387 Fed.Appx. 289, 292 (3d Cir. 2010). Plaintiff has alleged that he resides in and is a citizen of New Jersey and that Defendant Tri-Coast Pharmacy is incorporated in the state of and has its principal

place of business in Florida. (Doc. No. 14, Am. Compl. at ¶¶ 1–3). Likewise, Plaintiff alleges that Defendant Kevin O’Connell resides in and is a citizen of the state of South Carolina. (*Id.* at ¶ 5). Damages are alleged to be in excess of \$75,000. (Doc. No. 14, Am. Compl.). Accordingly, because the Plaintiff and Defendants are citizens of different states and the amount in controversy exceeds the statutory threshold, this Court has diversity jurisdiction.

Turning to the issue of personal jurisdiction, if the court lacks personal jurisdiction over a defendant, the court does not have authority to render a default judgment, and any such judgment will be deemed void. *Budget Blinds, Inc. v. White*, 536 F.3d 244, 258 (3d Cir. 2008). In the absence of an evidentiary hearing, a plaintiff’s complaint need only establish a prima facie case of personal jurisdiction. *Allaham v. Naddaf*, 635 F. App’x 32, 36 (3d Cir. 2015). A district court sitting in diversity may assert personal jurisdiction over a nonresident defendant to the extent allowed under the law of the forum state. New Jersey’s long-arm statute allows the exercise of personal jurisdiction to the full extent permitted by the Constitution. Thus, the standard for a federal court sitting in diversity is whether a “defendant has minimum contacts, such that the exercise of jurisdictions comports with traditional notions of fair play and substantial justice.” *Allaham*, 635 F. App’x at 37.

There are two distinct theories under which personal jurisdiction can arise: general and specific. *Grimes v. Vitalink Commc’ns Corp.*, 17 F.3d 1553, 1559 (3d Cir. 1994). A court has general jurisdiction when a defendant has “continuous and systematic” contacts with the forum state. *O’Connor v. Sandy Lane Hotel Co.*, 496 F.3d 312, 317 (3d Cir. 2007). A court has specific jurisdiction when a plaintiff’s claim arises from a defendant’s actions within the forum state, such that the defendant could “reasonably anticipate being haled into [the state’s] court[s].” *Vetrotex Certainteed Corp. v. Consol. Fiber Glass Prods. Co.*, 75 F.3d 147, 151 (3d Cir. 1996).

Plaintiff does not allege that this Court has general jurisdiction over Defendant Tri-Coast Pharmacy and Kevin O’Connell. Rather, it appears Plaintiff is alleging that this Court has specific jurisdiction over Defendants because they allegedly sold the contaminated pharmaceuticals in numerous states, including New Jersey. (See Doc. No. 14, Am. Compl. at ¶ 16).

To satisfy federal due process limits, which are incorporated by the New Jersey long-arm statute, a defendant’s minimum contacts are examined in relation “to the nature of the interactions and type of jurisdiction asserted.” *Telcordia Tech Inc. v. Telkom SA Ltd.*, 458 F.3d 172, 177 (3d Cir. 2006). For specific jurisdiction, the Supreme Court has delineated three due process requirements: (1) the plaintiff must demonstrate that the defendant purposefully directed its activities at the forum; (2) the litigation must arise out of or relate to at least one of those activities; and (3) if the first two requirements are satisfied, a court may consider whether the exercise of jurisdiction otherwise “comports with fair play and substantial justice.” *Celgene Corp. v. Distinct Pharma*, No. 2:17-CV-5303-KM-JBC, 2019 WL 1220320, at *2 (D.N.J. Mar. 13, 2019).

Plaintiff has pled a prima facie case of specific jurisdiction. First, Plaintiff alleges that Defendants have purposefully directed their activities to New Jersey by selling the contaminated pharmaceuticals directly to consumers, including Plaintiff, in New Jersey. (See Doc. No. 14, Am. Compl. at ¶ 16). See *J. McIntyre Mach., Ltd. v. Nicastro*, 564 U.S. 873, 884–86 (2011) (noting the difference, for personal jurisdiction purposes, between directly selling products to a forum and products that end up in a forum because of the stream of commerce). Second, the litigation arises out of this activity because the products Defendants shipped to New Jersey are the very ones that caused Plaintiff’s injuries and allegedly violate New Jersey’s products liability and consumer protection statutes. Third, the exercise of jurisdiction comports with “fair play and substantial justice.” Factors that are considered in this inquiry include “the burden on the defendant,” “the

forum State’s interest in adjudicating the dispute,” “the plaintiff’s interest in obtaining convenient and effective relief,” “the interstate judicial system’s interest in obtaining the most efficient resolution of controversies,” and the “shared interest of the several States in furthering fundamental substantive social policies.” *World-Wide Volkswagen Corp. v. Woodson*, 444 U.S. 286, 292 (1980); *see also Burger King Corp. v. Rudzewicz*, 471 U.S. 462, 477 (1985). These factors do not weigh against finding personal jurisdiction.

B. Entry of Default

Second, the Court must ensure that the entry of default under Rule 55(a) was appropriate. Rule 55(a) directs the Clerk of the Court to enter a party’s default when the party “against whom a judgment for affirmative relief is sought has failed to plead or otherwise defend, and that failure is shown by affidavit or otherwise.” Here, Plaintiff certified service of Defendants on December 6, 2018. (Doc. No. 4). Defendants have made no attempt to answer or defend the action. Accordingly, the Clerk appropriately issued the entry of default under Rule 55(a) on March 2, 2020. (Doc. No. 17).

C. Fitness of Defendant

Third, the Court must confirm that the defaulting parties are not infants or incompetent persons, or persons in military service exempted from default judgment. *See* Fed. R. Civ. P. 55(b)(2); 50 U.S.C.A. § 3931. Section 3931(b)(1) requires Plaintiff to file an affidavit “stating whether or not the defendant is in military service and showing necessary facts to support the affidavit” before the Court can enter default judgment for the plaintiff. Neither of these requirements apply to Defendant Tri-Coast Pharmacy because it is a corporation. Thus, Tri-Coast Pharmacy is fit for default judgment.

These requirements do apply to Defendant O’Connell, however. Plaintiff has satisfied the first requirement because he alleged, upon information and belief, that Defendant Kevin O’Connell is not an infant nor incompetent. This affirmation is sufficient to comply with Rule 55(b)(2). *Fogarty v. Household Fin. Corp. III*, No. CV 14-4525 (RBK/JS), 2017 WL 748330, at *3 (D.N.J. Feb. 27, 2017). However, Plaintiff’s averment that “to my best information and belief defendants are not currently in active military service” is plainly insufficient to satisfy Section 3931(b)(1)’s requirement that “facts support the affidavit.” Plaintiff’s affidavit contains no facts regarding Defendant’s military service, his current whereabouts, fails to provide “any hint as to the efforts exerted in determining Defendant’s military status,” and Plaintiff’s counsel has not submitted proper documentation from the Department of Defense Manpower Data Center. *House v. Smith*, No. 2:18-CV-04283, 2020 WL 5118047, at *2 (E.D. Pa. Aug. 31, 2020). Accordingly, the Court will not proceed further with the default judgment analysis with respect to Defendant Kevin O’Connell but will proceed with the analysis for Tri-Coast Pharmacy. Plaintiff’s motion for default judgment will be denied without prejudice as it pertains to Defendant Kevin O’Connell.

D. Plaintiff’s Cause of Action

Fourth, the Court must determine whether Plaintiff’s complaint states a proper cause of action against Defendant Tri-Coast Pharmacy. The Court should accept well-pleaded factual allegations while disregarding mere legal conclusions. *DirecTV v. Asher*, No. 03-1969, 2006 WL 680533, at *1 (D.N.J. Mar. 14, 2006). This is because by virtue of the defendant’s default he is deemed to admit to well-pleaded factual allegations, but “is not held to admit facts that are not well-pleaded or to admit conclusions of law.” *Cotton v. Massachusetts Mut. Life Ins. Co.*, 402 F.3d 1267, 1278 (11th Cir. 2005) (alteration omitted) (quoting *Nishimatsu Constr. Co. v.*

Houston Nat'l Bank, 515 F.2d 1200, 1206 (5th Cir. 1975)); *DirecTV v. Asher*, No. 03-1969, 2006 WL 680533, at *1 (D.N.J. Mar. 14, 2006) (explaining that “[e]ven after default ... it remains for the court to consider whether the unchallenged facts constitute a legitimate cause of action, since a party in default does not admit mere conclusions of law.”). Plaintiff asserts eight causes of action against Defendant Tri-Coast Pharmacy, specifically: (1) violations of the New Jersey Products Liability Act; (2) breach of implied warranties; (3) breach of express warranties; (4) negligence; (5) negligence per se; (6) fraud under the New Jersey Consumer Fraud Act and N.J.S.A. § 56:8-1; (7) intentional infliction of emotional distress; and (8) negligent infliction of emotional distress. With the exception of the breach of express warranty and violation of the NJPLA claims, all other claims are subsumed under the NJPLA because they are causes of action for harm caused by a product.

i. Subsumption Under the New Jersey Products Liability Act

In implementing the New Jersey Products Liability Act, the Legislature intended “to limit the expansion of products-liability law” and “to limit the liability of manufacturers so as to balance[] the interests of the public and the individual with a view towards economic reality.” *Hindermeyer v. B. Braun Med. Inc.*, 419 F. Supp. 3d 809, 817 (D.N.J. 2019) (quoting *Zaza v. Marquess & Nell, Inc.*, 144 N.J. 34, 48 (1996)). To strike this balance, the NJPLA “established the sole method to prosecute a product liability action” and thus “effectively create[d] an exclusive statutory cause of action for claims falling within its purview.” *Tirrell v. Navistar Int'l, Inc.*, 248 N.J. Super. 390, 398–99 (App. Div. 1991); *Repola v. Morbark Indus., Inc.*, 934 F.2d 483, 492 (3d Cir. 1991). As such, “the NJPLA generally subsumes common law product liability claims, thus establishing itself as the sole basis of relief under New Jersey law available to

consumers injured by a defective product.” *Repola v. Morbark Indus., Inc.*, 934 F.2d 483, 492 (3d Cir. 1991).

The rule that the NJPLA subsumes almost all other causes of action stems from the language of the statute itself. Specifically, N.J.S.A. 2A:58C–2 states:

A manufacturer or seller of a product shall be liable in a product liability action only if the claimant proves by a preponderance of the evidence that the product causing the harm was not reasonably fit, suitable or safe for its intended purpose because it: a. deviated from the design specifications, formulae, or performance standards of the manufacturer or from otherwise identical units manufactured to the same manufacturing specifications or formulae, or b. failed to contain adequate warnings or instructions, or c. was designed in a defective manner.

N.J.S.A. 2A:58C–2. Under the definition section of the statute, “harm” is defined as “(a) physical damage to property, other than to the product itself; (b) personal physical illness, injury or death; (c) pain and suffering, mental anguish or emotional harm; and (d) any loss of consortium or services or other loss deriving from any type of harm described in subparagraphs (a) through (c) of this paragraph.” N.J.S.A. § 2A:58C-1(b)(2). Further, a “product liability action” is defined as “any claim or action brought by a claimant for harm caused by a product, irrespective of the theory underlying the claim, except actions for harm caused by breach of an express warranty.” N.J.S.A. § 2A:58C-1(b)(3).

From these provisions, courts have concluded that a claim is subsumed by the NJPLA if: (1) it is brought by a claimant for harm caused by a product, regardless of the theory underlying the claim; and (2) the harm suffered if of a type listed in the definitional section. *Hindermeyer v. B. Braun Med. Inc.*, 419 F. Supp. 3d 809, 818 (D.N.J. 2019). But “courts do not simply determine whether or not the victim’s injury was literally ‘caused by a product.’” Rather, they look at the “essence of the claims and decide whether the plaintiff is disguising what would traditionally be considered a products liability claim as an alternative cause of action.” *New Hope*

Pipe Liners, LLC v. Composites One, LCC, No. CIV. 09-3222, 2009 WL 4282644, at *2 (D.N.J. Nov. 30, 2009) (noting if the language of the PLA were taken literally, it would subsume every cause of action that involved someone committing a battery with a commercially-made object because “the victim [undoubtedly] suffers ‘harm caused by a product’” but no one maintains that the PLA has subsumed the tort of battery); *see also Universal Underwriters Ins. Grp. v. Pub. Serv. Elec. & Gas Co.*, 103 F. Supp. 2d 744, 748 (D.N.J. 2000) (finding that the plaintiff’s negligence claim did not fall under the NJPLA, where “the claim asserted by the Plaintiff [was] not related to a defect in the product (i.e. the electricity), but rather to the maintenance and oversight of PSE & G’s emergency response service.”). With these principles in mind, we turn to Plaintiff’s claims.

Plaintiff’s claims arise out of the personal injuries he suffered as a result of using the contaminated pharmaceutical. The gravamen of the complaint is that Tri-Coast Pharmacy’s failure to maintain a sterile and clean environment resulted in the manufacture of contaminated pharmaceuticals and Plaintiff’s use of these pharmaceuticals ultimately caused his bacterial infection and infective synovitis of the wrist. While Plaintiff attempts to shoehorn his allegations into other causes of action, it is clear from the innumerable boilerplate allegations that his claims sound in products liability causes of action. For instance, Plaintiff alleges Tri-Coast Pharmacy violated New Jersey’s Consumer Fraud Act along with N.J.S.A. 56:8-1 et. seq., when it represented on its website that it “pride[s] [itself] in offering services and compounds that are prepared with the utmost integrity to the rules and regulations set forth by USP Chapter 797” because it knew that Plaintiff’s pharmaceuticals were not prepared in this manner and did not comply with these regulations. Whatever the merits of these two claims, it is axiomatic that they are premised on the product being defective because the alleged misrepresentation would not be

actionable if Tri-Coast Pharmacy's pharmaceuticals were not contaminated. *See Sun Chem. Corp. v. Fike Corp.*, 981 F.3d 231, 234 (3d Cir. 2020) (concluding the corporation's claim under the CFA was not subsumed because even if the product was not defective, the corporation would still have a claim under the CFA based on the alleged misrepresentations). Thus, Plaintiff's claims under the New Jersey CFA and N.J.S.A. 56:8-1 et. seq. are subsumed by the PLA.

Plaintiff's claims for breach of implied warranty, negligence, negligence per se, intentional infliction of emotional distress, and negligent infliction of emotional distress fare no better.¹ Plaintiff alleges Tri-Coast Pharmacy was negligent in, among other things, manufacturing a pharmaceutical that was unsafe and contaminated with harmful fungus, failing to warn users of the unsafe and hazardous conditions of the pharmaceutical drugs, and failing to test and inspect the drugs. Plaintiff further alleges Tri-Coast Pharmacy was negligent per se because it violated "various State and Federal standards, regulations and requirements." In addition to Plaintiff's averments not being sufficient to state a claim for negligence per se, both the negligence and negligence per se claims are premised on the Defendant's alleged manufacture, design and sale of the contaminated pharmaceutical which brings them within the ambit of the PLA. *See Hindermeyer v. B. Braun Med. Inc.*, 419 F. Supp. 3d 809, 823 (D.N.J. 2019) (concluding the negligence claim was subsumed by the NJPLA because it was based on the defendant's alleged manufacture of a defective blood clot filter and not on the independent conduct of the defendant). The breach of implied warranty claim is also subsumed because it is alleging harm caused by the pharmaceutical, rather than harm from the malfunction of the pharmaceutical itself. *Montich v. Miele USA, Inc.*, 849 F. Supp. 2d 439, 457 (D.N.J. 2012)

¹ Not only does Plaintiff recite boilerplate legal conclusions but the allegations do not support the claims. For instance, Plaintiff alleges Defendants acted in an extreme and outrageous manner by "deceiving hospitals, physicians, buyers, consumers, and patients." The Court is not sure how the deception as to *others* caused *Plaintiff's* alleged emotional distress.

(concluding the breach of implied warranty claim was not subsumed by the NJPLA because the plaintiff's alleged harm pertained to the malfunctioning of the washing machine itself rather than harm that was caused by the washing machine). Lastly, the IIED and NIED claims, which essentially allege that Tri-Coast Pharmacy was aware of the contamination but failed to disclose it, are subsumed because they amount to failure to warn claims. *Sun Chem. Corp. v. Fike Corp.*, 243 N.J. 319, 339 (2020) (explaining "claims that sound in the type of products liability actions defined in the PLA must be brought under the PLA."); *Indian Brand Farms v. Novartis Crop Prot., Inc.*, 890 F. Supp. 2d 534, 548 (D.N.J. 2012) (finding plaintiff's fraud-based claims were subsumed by the NJPLA because they were based on facts that supported a failure to warn claim).

Accordingly, Plaintiff's claims for: (1) negligence; (2) negligence per se; (3) fraud under the New Jersey Consumer Fraud Act and N.J.S.A. § 56:8-1; (4) intentional infliction of emotional distress; (5) negligent infliction of emotional distress; and (6) breach of implied warranty are subsumed under the NJPLA.

ii. Violation of the New Jersey Product's Liability Act

In the Complaint, Plaintiff appears to allege claims for design defect, manufacturing defect, and failure to warn under the NJPLA. To plead a prima facie case under the NJPLA, a plaintiff must show that: (1) the product was defective; (2) the defect existed when the product left the hands of the defendant; (3) the defect proximately caused injuries to the plaintiff; and (4) the injured plaintiff was a reasonably foreseeable user. *Myrlak v. Port Auth. of New York & New Jersey*, 157 N.J. 84, 97 (N.J. 1999). A product is deemed defective when "it is not reasonably fit, suitable, or safe for the ordinary or foreseeable purpose for which it is sold." *Id.* This standard of liability can be established by demonstrating that there is: (1) a manufacturing defect; (2) a

design defect; or (3) inadequate warnings or instructions. *Kemly v. Werner Co.*, 151 F. Supp. 3d 496, 505 (D.N.J. 2015).

Plaintiff has satisfied elements two, three, and four. He alleges, upon information and belief, that at the time the pharmaceutical were placed into the stream of commerce they were contaminated and lacked adequate warnings. (Doc. No. 14, Am. Compl. at ¶ 43). He further asserts the contaminated pharmaceuticals were the proximate cause of his bacterial infection and infective synovitis of the wrist. (*Id.* at ¶ 45). Additionally, Plaintiff avers that Defendant Tri-Coast Pharmacy knew that its pharmaceuticals would reach patients, including Plaintiff, after they were placed into the stream of commerce. (*Id.* at ¶ 35). It is a closer call, however, whether Plaintiff has alleged sufficient facts to support an inference that the product is defective.

To establish a prima facie case of design defect, the plaintiff must assert that the product could have been designed more safely and present, under a risk-utility analysis, the existence of an alternative design that is both practical and feasible. *Mendez v. Shah*, 28 F. Supp. 3d 282, 297 (D.N.J. 2014). A plaintiff may pursue a design defect claim by contending that its risks outweigh its harm, or that an alternative design exists. *Id.* While there is no “pre se rule that [p]laintiffs must, under all circumstances, provide a reasonable alternative design,” a plaintiff must plead either that the product’s risk outweighs its harm, or that an alternative design exists, in order to state a claim for a design defect under the PLA. *Smith v. Keller Ladder Co.*, 275 N.J.Super. 280, 284 (App.Div.1994) (stating that to establish prima facie case of design defect, plaintiff must demonstrate availability of technologically feasible and practical alternative design that would have reduced or prevented plaintiff's harm).

Here, while Plaintiff’s allegations border on legal conclusions, he has managed to plead enough facts to eke out a claim for a design defect. Plaintiff asserts the pharmaceutical was

defectively designed because “it was developed, mixed and/or created in an insanitary and unsafe environment that contained or promoted the development of harmful organisms such as bacteria, which was . . . unreasonably dangerous.” (Doc. No. 14, Am. Compl. at ¶ 36). While not stated in explicit terms, this allegation is sufficient to constitute an assertion that the risk of using the contaminated pharmaceutical outweighs its utility. *Fabricant v. Intamin Amusement Rides Int. Corp. Est.*, No. CV 19-12900, 2020 WL 373348, at *4 (D.N.J. Jan. 23, 2020) (reasoning that while the plaintiff did not explicitly weigh the utility and risks of Kingda Ka’s component parts, he did so indirectly when he described the “unreasonable risk of whiplash injury to the vertebrae of [riders’] necks and spines.”). Therefore, Plaintiff has stated a claim for design defect.²

In a failure to warn case, the duty to warn is premised on the notion that a product is defective absent an adequate warning for foreseeable users that the product can potentially cause injury. *Clark v. Safety-Kleen Corp.*, 179 N.J. 318, 336, 845 A.2d 587 (2004) (quoting *Coffman v. Keene Corp.*, 133 N.J. 581, 628 A.2d 710 (1993)). A warning is adequate if it is “one that a reasonably prudent person in the same or similar circumstances would have provided with respect to the danger and that communicates adequate information on the dangers and safe use of the product.” *Banner v. Hoffmann-La Roche Inc.*, 383 N.J. Super. 364, 375, 891 A.2d 1229 (App. Div. 2006). The plaintiff must establish that the defendant had a duty to warn, and then establish that an adequate warning was not provided. *James v. Bessemer Processing Co.*, 155 N.J. 279,

² We do note that Plaintiff’s allegation regarding a reasonable alternative design is wholly inadequate because it is conclusory and unsupported by any facts. Plaintiff alleges that an alternative design exists because “[a]t the time the pharmaceutical . . . was designed . . . and sold to Plaintiff, safer reasonably feasible safeguards and safety standards and procedures were utilized by other pharmacists . . . which represented the standard of care, and which if Defendants had followed would have prevented or minimized the risk to Plaintiff.” *Nelson v. Biogen Idec Inc.*, No. CIV.A. 12-7317, 2013 WL 1700918, at *1 (D.N.J. Apr. 19, 2013) (dismissing design defect claim because the conclusory allegation that “[a]t the time Tysabri® left the hands of Defendants, there were safer alternative designs that were economically and technologically feasible by the application of reasonable scientific knowledge” was insufficient to demonstrate the existence of a reasonable alternative design).

714 A.2d 898, 907 (1998). Plaintiff must then prove the breach of duty (the absence of a warning) was a proximate cause of the accident.

Similarly, although Plaintiff's pleadings for the failure to warn claim are minimal, they are sufficient to state a plausible claim for relief. Plaintiff alleges "[a]t the time the pharmaceutical and prescription drug material and/or medication was designed . . . and sold to Plaintiff, Defendants knew . . . that the material was . . . contaminated with bacteria." (Doc. No. 14, Am. Compl. at ¶ 53). This allegation is sufficient to establish that Defendant had a duty to warn. *Fellner v. Tri-Union Seafoods, L.L.C.*, No. CIVA06-CV-0688(DMC), 2010 WL 1490927, at *5 (D.N.J. Apr. 13, 2010) (concluding the assertion that the defendant "was aware that its tuna products contained methylmercury . . . that could result in mercury poisoning" was sufficient to demonstrate that the defendant had knowledge). Plaintiff then alleges Defendant Tri-Coast Pharmacy's warnings were inadequate because it failed to "warn users of the defective and/or hazardous conditions of the pharmaceutical and prescription drug material" and "fail[ed] to provide timely and adequate post-marketing warnings and instructions after they knew of the risk of harm from the pharmaceutical and prescription drug material." (Doc. No. 14, Am. Compl. at ¶ 38m, h). These allegations are tantamount to an assertion that Defendant failed to warn about the presence of harmful bacterial contaminants in its products. They too are sufficient to establish an inadequate warning. *Id.* (concluding the allegation that defendant "concealed, suppressed, omitted, and/or failed to disclose material information regarding the presence of methylmercury and/or other harmful compounds in its Tuna Products" was sufficient to state a plausible claim for failure to warn). Finally, Plaintiff has alleged the pharmaceutical's inadequate warnings were the proximate cause of his injuries. Therefore, Plaintiff has made out a plausible failure to warn claim.

A manufacturing defect exists if the product “deviated from the design specification, formulae, or performance standards of the manufacturer or from otherwise identical units manufactured to the same manufacturing specifications or formulae.” *Vicente v. Johnson & Johnson*, No. CV201584KMJBC, 2020 WL 7586907, at *10 (D.N.J. Dec. 21, 2020). To determine whether a product contains a manufacturing defect, the “product may be measured against the same product as manufactured according to the manufacturer’s standards.” *Mickens v. Ford Motor Co.*, No. 10–cv–05842, 2011 WL 3444055, at *3 (D.N.J.2011) (citing *Navarro v. George Koch & Sons, Inc.*, 211 N.J.Super. 558, 512 A.2d 507, 517 (1986)). “If the particular product used by the plaintiff fails to conform to those standard or other units of the same kind, it is a manufacturing defect.” *Id.*

Under New Jersey law, the plaintiff need not prove the nature or etiology of the manufacturing defect with scientific precision. *Vicente v. Johnson & Johnson*, No. CV201584KMJBC, 2020 WL 7586907, at *11 (D.N.J. Dec. 21, 2020). “Rather, because the evidence of a flaw in the manufacturing process is uniquely within the knowledge and control of the manufacturer, ‘[p]roof that a product is not fit for its intended purposes ‘requires only proof . . . that ‘something was wrong’ with the product.’” *Id.* (quoting *Myrlak v. Port Auth. of New York & New Jersey*, 723 A.2d 45, 52 (1999)).

While Plaintiff’s allegations are razor thin, they are enough to state a plausible claim for relief for a manufacturing defect. Like the design defect claim, Plaintiff alleges the product was defectively manufactured because “it was developed, mixed and/or created in an insanitary and unsafe environment that contained or promoted the development of harmful organisms such as bacteria.” (Doc. No. 14, Am. Compl. at ¶ 36). Plaintiff further alleges that Defendant Tri-Coast Pharmacy “fail[ed] to ensure the manufacture and/or compounding of the pharmaceutical and

prescription drug material in a sterile environment” and failed to “to inspect the manufacturing . . . environment to ensure that it [was] sterile, clean and safe.” (*Id.* at ¶¶ 38i, j). Plaintiff then concludes that the “pharmaceutical and prescription drug material and/or medication, as manufactured, compounded, and designed, deviated from the design specifications, formulae or performance standards of other pharmacists and/or manufacturers. . . in that the subject pharmaceutical and prescription drug material did not include all necessary safety features that would prevent the product from causing injury.” (*Id.* at ¶ 49). While this is a close call, Plaintiff’s common-sense allegations that Defendant Tri-Coast Pharmacy failed to inspect and ensure that the pharmaceuticals were manufactured in a sterile environment support the inference that the product failed to conform to the manufacturer’s standards. Therefore, Plaintiff has pled a plausible manufacturing defect claim.

iii. Breach of Express Warranty

To state a claim for breach of express warranty under New Jersey law, a plaintiff must allege the following three elements: “(1) that Defendant made an affirmation, promise or description about the product; (2) that this affirmation, promise or description became part of the basis of the bargain for the product; and (3) that the product ultimately did not conform to the affirmation, promise or description.” *Snyder v. Farnam Companies, Inc.*, 792 F. Supp. 2d 712, 721 (D.N.J. 2011). Under the New Jersey U.C.C., N.J.S.A. 12A:2-313, an “express warranty” is:

- (a) Any affirmation of fact or promise made by the seller to the buyer which relates to the goods and becomes part of the basis of the bargain creates an express warranty that the goods shall conform to the affirmation or promise.
- (b) Any description of the goods which is made part of the basis of the bargain creates an express warranty that the goods shall conform to the description.
- (c) Any sample or model which is made part of the basis of the bargain creates an express warranty that the whole of the goods shall conform to the sample or model.

N.J.S.A. 12A:2-313. “A statement can amount to a warranty, even if unintended to be such by the seller, if it could fairly be understood ... to constitute an affirmation or representation that the [product] possesse[s] a certain quality or capacity relating to future performance.” *Volin v. General Electric Company*, 189 F. Supp. 3d 411, 420 (D.N.J. 2016) (citations omitted). “[S]tatements that are nothing more than mere puffery are not considered specific enough to create an express warranty.” *Snyder*, 792 F. Supp. 2d at 721.

Plaintiff has failed to state a viable claim for breach of express warranty because he has not identified specific affirmations made by Defendants and has merely provided “bald assertions.” *Simmons v. Stryker Corp.*, Civ. No. 08–3451, 2008 WL 4936982, at *2, 2008 U.S. Dist. LEXIS 93306, at *5 (D.N.J. Nov. 17, 2008) (dismissing a claim that was “devoid of any factual matter to support the existence of an express warranty”); *Parker v. Howmedica Osteonics Corp.*, Civ. No. 07–2400, 2008 WL 141628, at *6, 2008 U.S. Dist. LEXIS 2570, at * 21 (D.N.J. Jan. 14, 2008) (general references to “press releases” and “assurances of safety,” as opposed to specific statements, cannot survive a motion to dismiss); *Heisner v. Genzyme Corp.*, No. 08–C–593, 2008 WL 2940811, at *8–9, 2008 U.S. Dist. LEXIS 60569, at *24–25 (N.D.Ill., July 25, 2008) (claim dismissed where plaintiff failed to specify any particular affirmation or promise by defendant). The allegations set forth under Count III for the breach of express warranty claim amount to nothing more than a recitation of the elements of the cause of action. Plaintiff alleges “Defendants expressly warranted that the pharmaceutical and prescription drug material . . . was safe and appropriate for its intended application,” and in reliance on this express warranty, Plaintiff “agreed to allow the pharmaceutical and prescription drug . . . to be injected . . . into his body.” (Doc. No. 14, Am. Compl. at ¶¶ 66, 67). He further asserts that “Defendant breached [this warranty] contained on their labeling and/or containers [by] manufacturing . . . selling . . . and

marketing the pharmaceutical . . . in an unsafe, defective . . . and unmerchantable condition.” (*Id.* at ¶ 69). While a defendant’s default will result in admission of factual allegations, this same principle does not apply to legal conclusions. Therefore, because Plaintiff’s allegations amount to legal conclusions, he has failed to plead a proper cause of action for breach of express warranty against Defendant Tri-Coast Pharmacy.

E. Emasco Factors

Fifth, the Court must consider the *Emasco* factors: (1) whether the defaulting party has a meritorious defense; (2) whether Plaintiff will suffer prejudice if default is denied; and (3) whether the defaulting party is culpable in bringing about default. *Chamberlain v. Giampapa*, 210 F.3d 154, 164 (3d Cir. 2000); *Emasco Ins. Co. v. Sambrick*, 834 F.2d 71, 74 (3d Cir. 1987).

i. Meritorious Defense

The showing of a meritorious defense is accomplished when “allegations of defendant’s answer, if established on trial, would constitute a complete defense to the action.” *United States v. \$55,518.05 in U.S. Currency*, 728 F.2d 192, 195 (3d Cir. 1984). If the defendant does not respond, the Court cannot determine whether the defendant has any meritorious defenses, and the factor points in favor of granting default judgment against the defendant. *Teamsters Health & Welfare Fund of Philadelphia v. Dubin Paper Co.*, No. 11-7137, 2012 WL 3018062, at *4 (D.N.J. July 24, 2012). Here, Defendant has not articulated a meritorious defense because it has not appeared, answered or defended itself. Thus, this factor points towards granting Plaintiff’s motion for default judgment against Defendant.

ii. Prejudice to Plaintiff

Prejudice occurs when “a plaintiff has no other means to vindicate rights and recover damages.” *Trs. of the BAC Local 4 Pension Fund v. Danaos Group LLC*, No. 18-15551, 2019 WL

3453270, at *2 (D.N.J. July 31, 2019). If a plaintiff is unable to prosecute its case, engage in discovery, or obtain a final outcome on its claims—whatever that outcome might be—it will face prejudice in being denied default judgment. *Id.* However, delay in obtaining an outcome will not be sufficient to deny a motion by the defendant to vacate a default judgment. *Gant v. Advanced Elec., Inc.*, No. 16-1954, 2017 WL 3638762, at *2 (D.N.J. Aug. 23, 2017). Here, because Tri-Coast Pharmacy has failed to appear or answer, Plaintiff will suffer prejudice if it does not receive default judgment because it has no other means of vindicating its claim. Additionally, Defendant has not moved to vacate default judgment. Thus, this factor points towards granting Plaintiff’s motion for default judgment against Defendant Tri-Coast Pharmacy.

iii. Defendant’s Culpability

Culpable conduct is conduct that displays “willfulness” or “bad faith” and amounts to “more than mere negligence.” *Mrs. Ressler’s Food Prods. v. KZY Logistics LLC*, 675 F. App’x 136, 142 (3d Cir. 2017). Culpable conduct can be shown by a “reckless disregard for repeated communications from plaintiffs and the court.” *Nationwide Mut. Ins. Co. v. Starlight Ballroom Dance Club, Inc.*, 175 F. App’x 519, 523 (3d Cir. 2006). In fact, if a defendant fails to answer, move, or otherwise respond to an action, culpability will be presumed. *See Teamsters Health*, 2012 WL 3018062, at *4 (holding defendant’s failure to answer demonstrated a presumption of culpability). However, innocence or a mere mistake will not show culpable conduct. *Nationwide*, 175 F. App’x at 523.

Here, the Court will presume culpability on part of Defendant Tri-Coast Pharmacy because it has failed to respond, answer, or involve itself in this case in any way and it has done nothing to overcome this presumption. At no point during this action has Defendant Tri-Coast Pharmacy

answered any filing. Thus, all of the Emasco factors point towards granting Plaintiff's motion for default judgment against Defendant Tri-Coast Pharmacy.

F. Damages

Finally, the Court must determine the appropriate amount of damages to be awarded. Under Rule 55(b)(1), when a plaintiff's claim against a defendant is for "a sum certain or for a sum which can by computation be made certain, the Clerk upon request of the plaintiff and upon affidavit of the amount due shall enter Judgment for the amount and costs against defendant, if the defendant has been defaulted for failure to appear and if he is not an infant or incompetent person." The Court may order a plaintiff to provide additional clarifying information to justify the damages sought or conduct a hearing to determine the amount of damages owed by the defendant. *Doe*, 2013 WL 3772532, at *2. However, the Court is not required to hold a hearing when the plaintiff has adequately provided affidavits and documentary evidence supporting its claim for damages. *Id.* at *3. Thus, if the damages are a certain sum, further evidentiary inquiry is not required for a district court to enter final judgment. *Bds. of Trs. Of the Operating Eng'rs Local 825 Welfare Fund v. Robert Silagy Landscaping, Inc.*, No. 06-1795, 2006 WL 3308578 (D.N.J. Nov. 13, 2006).

Plaintiff's claims are not for a sum certain. Therefore, as requested, a hearing to assess damages is necessary and a separate order shall issue setting forth the date of the hearing. The plaintiff will be required to put forth evidence regarding the specific amounts of damages requested.

IV. Conclusion

Plaintiff's Motion for Default Judgment as to Defendant Kevin O'Connell is **DENIED** without prejudice because he has failed to show that Defendant is fit for default judgment. While

Plaintiff's Motion for Default Judgment against Defendant Tri-Coast Pharmacy for the manufacturing defect, design defect, and failure to warn claims have satisfied all requirements for the motion to be granted, this Court cannot enter a final judgment against Tri-Coast Pharmacy until the breach of express warranty claim has been withdrawn or resolved. *U.S. Golf Ass'n v. ISaAC Scoring Sys., LLC*, No. CIV. 09-1848, 2010 WL 323203, at *3 (D.N.J. Jan. 20, 2010) (noting "[u]ntil these claims have been either resolved or withdrawn, the Court cannot enter final judgment."); *Qingwei Ma v. Chef Jon's Authentic Chinese Cuisine*, No. CV177379ESJAD, 2020 WL 6111037, at *6 (D.N.J. Oct. 16, 2020) (concluding the plaintiff had stated a claim against the defendant under the Fair Labor Standards Act and New Jersey Wage and Hour Law but denying the motion for default judgment without prejudice because it could not enter a final judgment until the breach of contract and unjust enrichment claims were resolved or withdraw). Therefore, Plaintiff's Motion for Default Judgment against Defendant Tri-Coast Pharmacy will be **DENIED** without prejudice as well. Plaintiff is instructed to inform the Court in writing within the next thirty (30) days whether it intends to resolve the remaining claim or dismiss it. If Plaintiff does not intend to pursue the breach of express warranty claim against Tri-Coast Pharmacy, the Court will enter default judgment against Tri-Coast Pharmacy, hold a hearing for the assessment of damages, and dismiss that claim.

Dated: 2/10/2021

s/ Robert B. Kugler

 ROBERT B. KUGLER

United States District Judge